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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
KUBELIK, ANNE R	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 10/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,979	CAROZZI ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2006 and 25 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,19 and 22-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,19 and 22-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11, 19 and 22-25 are pending.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The objections to claims 2 and 11 are withdrawn in light of Applicant's amendment of the claims.

4. The rejection of claims 22 and 24 under 35 U.S.C. 102(b) as being anticipated by Barton et al (US Patent 6,833,449, filed August 1989) is withdrawn in light of Applicant's amendment of the claims.

Claim Rejections - 35 USC § 112

5. Claims 1-11, 19 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleic acids encoding SEQ ID NO:3 and 5, host cells, plants, plant cells and seeds comprising them, and method of using them to make SEQ ID NO: 3and 5, does not reasonably provide enablement for nucleic acids encoding SEQ ID NO:7, nucleic acids encoding pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7, nucleic acids with 95% identity to SEQ ID NO:1, 2, 4, or 6, host cells, plants, plant cells and seeds comprising them, and method of using them to make a pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7 and a pesticidal protein encoded by a nucleic acid with 95% identity to SEQ ID NO:1, 2, 4 or 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as

set forth in the Office action mailed 14 February 2006. Applicant's arguments filed 12 May 2005 have been fully considered but they are not persuasive.

The claims are broadly drawn to nucleic acids encoding a pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7, nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6, or a complement of those nucleic acids, host cells, plants, plant cells and seeds comprising them, and method of using them to make a pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7 and a pesticidal protein encoded by a nucleic acid with 95% identity to SEQ ID NO:1, 2, 4 or 6.

The instant specification, however, only discusses sequencing of DNAs from non-publically available bacterial strain ATX13026 (examples 1-4), identification of a nucleic acid, SEQ ID NO:1, that encodes a protein, SEQ ID NO:3, with 66% identity to the delta endotoxin cry40Aa, and an alternate start site variant, SEQ ID NO:4, which encodes SEQ ID NO:5 (examples 5-6), identification of an open reading frame, SEQ ID NO:7, encoded by SEQ ID NO:6, downstream of SEQ ID NO:1 with identity to downstream open reading frames of other cry proteins (example 7); assay of SEQ ID NO:3 for pesticidal activity against *Trichoplusa ni* (cabbage looper) and *Tenebrio molitor* (yellow mealworm) (examples 8-11), and prophetic guidance for expression in plants (examples 12-14).

The instant specification fails to provide guidance for how to make nucleic acids encoding pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7 and nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6.

The instant specification fails to provide guidance for which amino acids of SEQ ID NO:3, 5 or 7 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain the activity of the encoded protein. The specification also fails to provide

guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein.

Making substitutions in a protein does not produce predictable results. Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Similarly, Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that when three histidines that are maintained in ADP-glucose pyrophosphorylase across several species are substituted with the "nonconservative" amino acid glutamine, there is little effect on enzyme activity, while the substitution of one of those histidines with the "conservative" amino acid arginine drastically reduced enzyme activity (see Table 1).

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding proteins with 95% identity to SEQ ID NO:3, 5 or 7 or nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6. Making all possible single amino acid substitutions in an 693 amino acid long protein like that encoded by SEQ ID NO:1 or 2 would require making and analyzing 19^{693} nucleic acids; these proteins would have 99.8%% identity to SEQ ID NO:3, 5 or 7. Nucleic acids encoding proteins with 95% identity to SEQ ID NO:3, 5 or 7 would encode proteins with 34 amino acid substitutions. Making all possible single nucleotide substitutions in an 5980 nucleic acid like that of SEQ ID NO:1 would require making and analyzing 4^{5980} nucleic acids and making all possible single nucleotide substitutions in an 2082 nucleic acid like that of SEQ ID NO:2 would require making and analyzing 4^{2208} nucleic acids. Nucleic acids with 95%

identity to SEQ ID NO:1 encompass those that encode proteins with 299 amino acid substitutions; these proteins would have 56% identity to SEQ ID NO:3, 5 or 7. Making all these nucleic acids without guidance as to which amino acid and nucleotide substitutions may be made means that many more than 19^{693} or 4^{5980} nucleic acids would need to be made and analyzed. Guo et al (2004, Proc. Natl. Acad. Sci. USA 101: 9205-9210) teach that while proteins are fairly tolerant to mutations resulting in single amino acid changes, increasing the number of substitutions additively increases the probability that the protein will be inactivated (pg 9209, right column, paragraph 2). Thus, making and analyzing proteins with up to 299 amino acid substitutions that also have pesticidal activity would require undue experimentation.

Making amino acid substitutions in *cry* proteins is unpredictable. Each *cry* protein only has activity against one or few insect species (de Maagd et al, 1999, Appl. Environ. Microbiol. 65:4369-4374, see pg 4369, column 1, paragraph 1). Even a single amino acid substitution in a *cry* protein may alter its insecticidal specificity, and toxicity must be determined empirically (Tounsi et al, 2003, J. Appl. Microbiol. 95:23-28; see pg 27, column 2, paragraph 2). For example, a conservative substitution of a lysine for an arginine in a cry11A protein eliminated toxicity to *Aedes aegyptii* (Angsuthanasombat et al, 2001, J. Biochem. Mol. Biol. 34:402-407, paragraph spanning the columns on pg 405).

AXMI-008 has the most similarity to a *cry* protein with toxicity to the dipteran mosquito (cry40Aa; see Ibarra et al, 2003, Appl. Environ. Microbiol. 69:5269-5274; abstract and Table 2). Its toxicity to Lepidopterans *T. ni* and the Coleopteran *T. molitor* suggests that AXMI-008 is a new class of *cry* toxin. Thus, given the novelty of AXMI-008 and the unpredictability making in amino acid substitutions in *cry* proteins, proteins with up to 299 amino acid substitutions

relative to SEQ ID NO:3, 5 or 7 would likely have a very different insect toxicity than AXMI-008, if such toxins could even be made. The specification does not teach the insect toxicity of such proteins. Therefore, one would not know how to use nucleic acids encoding proteins with up to 299 amino acid substitutions relative to SEQ ID NO:3, 5 or 7.

The specification does not teach how to use plants transformed with a nucleic acid encoding SEQ ID NO:7. The specification teaches that SEQ ID NO:7 has 86% identity to *cry40Aa orf2* and 85% identity to *cry39Aa orf2*, but neither the specification nor the prior art teach how to use such ORFs. The specification even states that "these proteins also share homology to the C-terminal non-toxic domain of *cry4Aa* and *cry4Ba*" (pg 38, lines 9-10). Thus, one of skill in the art would not expect SEQ ID NO:7 to have any toxicity towards insects, and would not know how to use nucleic acids encoding SEQ ID NO:7.

The specification fails to teach how to use a complement of nucleic acids encoding pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7 or nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6. Complements of DNA molecules are generally used in antisense suppression. Transforming strain ATX13026 with the complement of a nucleic acid encoding a pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7 or a nucleic acid with 95% identity to SEQ ID NO:1, 2, 4 or 6 could potentially produce a bacterial strain that does not express the pesticidal protein, but the specification does not teach how to use such a bacterial cell. Transforming the cell of any other organism or transforming a plant with the complement of a nucleic acid encoding a pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7 or a nucleic acid with 95% identity to SEQ ID NO:1, 2, 4 or 6, could not suppress the expression of an

endogenous protein, as such an endogenous protein would not be present in the cell. The specification does not teach how to use such a cell or plant.

As the specification does not describe the transformation of any plant with a pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7, nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6, or a complement of those nucleic acids, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with insect resistance, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

Applicant urges that specification provides guidance by limiting the percent identity and requiring a function; guidance is provided on pg 8-13 (response pg 11).

This is not found persuasive. The claims encompass nucleic acid that encode proteins up to 107 amino acid substitutions relative to SEQ ID NO:3. Limiting the percent identity of the claimed nucleic acid, requiring a function, and the guidance on pg 8-9 do not teach which amino acid substitutions may be made in the proteins. Guidance for determining percent identity does not teach the necessary and sufficient structural features of the claimed nucleic acids, and does not teach which amino acids could be substitutive with which other amino acids.

Applicant urges that Crickmore (1998) and a webpage teach that numerous δ-endotoxins were known at the time of filing; the molecular biological techniques were routine, and methods of assay are provided in the specification on pg 8 and Examples 7-8 (response pg 11).

This is not found persuasive. Because each *cry* protein only has activity against one or few insect species (de Maagd et al, pg 4369, column 1, paragraph 1), and because Tounsi teaches that even a single amino acid substitution in a *cry* protein may alter its insecticidal specificity (pg 27, column 2, paragraph 2), Crickmore and the specification do not provide guidance as to which 107 amino acid substitutions can be made in SEQ ID NO:3. The webpage could not be considered because a paper copy was not sent.

Further, see *Genentech, Inc. v. Novo Nordisk, A/S*, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that disclosure of a "mere germ of an idea does not constitute [an] enabling disclosure", and that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1027

> ... despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. Amgen argues that this is sufficient to support its claims; we disagree. This "disclosure" might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs. There may be many other genetic sequences that code for EPO-Type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

Applicant urges that one would only need to make the claimed variants and assay them for activity using routine methods; thus the amount of experimentation is not undue (response pg 11-12).

This is not found persuasive. Doing so would require undue experimentation because the specification does not provide guidance as to which 299 amino acid substitutions can be made in SEQ ID NO:3. Thus, one would need to randomly make nucleic acids encoding proteins with 299 amino acid substitutions and test them. Because this would require trail and error experimentation and because of the likelihood of failure (see Guo et al, pg 9209, right column,

paragraph 2), this experimentation would be undue. Furthermore, the specification teaches to function for SEQ ID NO:7 and does not teach an assay for it.

Applicant urges that in Lazar and Hill the alteration was designed to occur at a highly conserved amino acid and one would not be surprised that modification would lead to loss of function; furthermore, none of these proteins was a δ-endotoxin (response pg 12-13).

This is not found persuasive. The surprise in Lazar and Hill was that these highly conserved amino acids in these well-characterized proteins did not behave as expected, indicting that the conventional wisdom about using conserved amino acids to guide the making of amino acid substitutions is wrong. Applicant has not shown that δ-endotoxin behave differently from other proteins.

Applicant urges that they have disclosed pesticidal sequences, and fragments and variants thereof, and the art had additional δ-endotoxin sequences; one may align these sequences as described on pg 9-11 to see which areas are unlikely to tolerate mutation (response pg 13).

This is not found persuasive. None of the specificity-altering mutations of DeMaagd, Tounsi and Angsuthanasombat appear to fall within the conserved regions on pg 4 and Fig 1. The specification teaches no variants that do not encode SEQ ID NO:3, 5 or 7. Furthermore, the specification suggests that SEQ ID NO:7 would not be toxic to insects (pg 38, lines 9-10).

Applicant urges that Li et al and Morse et al teach detailed information about the structure of δ-endotoxins, which are very well characterized; these could be used to choose among modification to retain the structure of the resultant protein (response pg 13-14).

This is not found persuasive. Li et al do not provide guidance for making 299 amino acid substitutions in a 693 amino acid protein; Li et al only provided guidance for making truncations

and insertion of chymotrypsin cleavage sites. Furthermore, the protein taught by Li et al is a cry3Aa protein and that taught by Morse et al is a cry2Aa protein, which the proteins encoded by SEQ ID NO: 3, 5 and 7 are not. The instant inventors did not use Li et al or Morse et al to make 299 amino acid substitutions in a 693 amino acid protein to create a pesticidal protein.

Applicant urges that Guo teaches the probability that a random amino acid replacement will lead to protein inactivation, while the specification provides a rational method for designing δ-endotoxin variants that retain activity (response pg 14).

This is not found persuasive because given the lack of guidance in the specification for making 299 amino acid substitutions; one would have to make them randomly to make the claimed sequences.

Applicant urges that DeMaagd, Tounsi and Angsuthanasombat describe insertions in conserved regions and domains; further they support Applicant's assertion that one would know which residues would change the function of endotoxins, and thus would know which not to change to maintain function (response pg 15).

This is not found persuasive. First, Li et al teaches that there is no portion of a δ-endotoxin is not part of Domain 1, II or II (¶ spanning pg 815-186); thus, Applicant's arguments that the mutations made in DeMaagd, Tounsi and Angsuthanasombat change the function because they are part of one of these domains would suggest that no mutations could be made in SEQ ID NO:3 and 5, and certainly does not provide any guidance for making any nucleic acids with 95% identity to SEQ ID NO:1 and that encode a δ-endotoxin with 299 amino acid substitutions relative to SEQ ID NO:3.

Second, Tounsi teaches that even a single amino acid substitution in a *cry* protein may alter its insecticidal specificity, and toxicity must be determined empirically (pg 27, column 2, paragraph 2).

Further, each *cry* protein only has activity against one or few insect species (de Maagd et al, pg 4369, column 1, paragraph 1). AXMI-014 has the most similarity to *cry* proteins with toxicity to mosquito (cry40Aa and cry24Aa), but its toxicity to the Lepidopteran *Trichoplusia li* suggests that AXMI-014 is a new class of *cry* toxin. Thus, given the novelty of AXMI-014 and the unpredictability making in amino acid substitutions in *cry* proteins, proteins with up to 299 amino acid substitutions relative to SEQ ID NO:3, 5 or 7 would likely have a very different insect toxicity than AXMI-014, if such toxins could even be made. The specification does not teach the insect toxicity of such proteins.

Applicant urges that plant transformation is routine and is taught on pg 20-27 and examples 10-11 (response pg 16).

This is not found persuasive. Making the claimed nucleic acids requires undue experimentation; thus making plants and constructs comprising them requires undue experimentation. The rejection is not that plant transformation and expression cassettes per se requires undue experimentation, but that making the nucleic acid required for the claimed plants and expression cassettes is undue.

6. Claims 1-11, 19 and 22-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 14 February 2006. Applicant's arguments filed 12 May 2005 have been fully considered but they are not persuasive.

A full review of the specification indicates that nucleic acids encoding a pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7 and nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6, wherein the nucleic acid encodes a pesticidal protein are essential to the operation of the claimed invention. As nucleic acids encoding proteins with 95% identity to SEQ ID NO:3, 5 or 7 would encode proteins with 35 amino acid substitutions and nucleic acids with 95% identity to SEQ ID NO:1 encompass those that encode proteins with 299 amino acid substitutions relative to SEQ ID NO:3, 5 or 7, the claims are drawn to a broad genus of nucleic acids. The level of skill and knowledge in the art at the time of filing was such that no other proteins within the scope of the claims were known

The specification describes no relevant characteristics or motifs for the claimed nucleic acids other than identity to SEQ ID NO:1, 2, 4 or 6. At the time of filing it was known that each *cry* protein only has activity against one or few insect species (de Maagd et al, 1999, Appl. Environ. Microbiol. 65:4369-4374, see pg 4369, column 1, paragraph 1) and that even a single amino acid substitution in a *cry* protein may alter its insecticidal specificity (Tounsi et al, 2003, J. Appl. Microbiol. 95:23-28; see pg 27, column 2, paragraph 2), but the relationship between structure and pesticidal function was not known. Furthermore, the specification does not describe the structure required for the recited function, nor does it describe the structural features that distinguish pesticidal protein-encoding nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6 from other nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6 or pesticidal

proteins with 95% identity to SEQ ID NO:3, 5 or 7 from other proteins with 95% identity to SEQ ID NO:3, 5 or 7.

The only species reduced to practice in the specification is SEQ ID NO:1, 2, 4 or 6, which encodes SEQ ID NO:3, 5 or 7. Since the disclosure fails to describe the common attributes that identify members of the genus, and because the genus is highly variant, SEQ ID NO:1, 2, 4 or 6 alone is insufficient to describe the claimed genus.

Additionally, the specification does not describe a function for SEQ ID NO:7. The only reference to its function is that known proteins with identity to SEQ ID NO:7 "share homology to the C-terminal non-toxic domain of *cry4Aa* and *cry4Ba*" (pg 38, lines 9-10). No actual function is described.

Hence, Applicant has not, in fact, described nucleic acids encoding a pesticidal protein with 95% identity to SEQ ID NO:3, 5 or 7 and nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6, wherein the nucleic acid encodes a pesticidal protein, within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that the claims recite that the nucleic acid has 95% identity to SEQ ID NO:1, 2, 4 or 6 a nucleic acid encoding SEQ ID NO:3, 5 or 7 and methods of assaying a determining percent identity are known in the art and taught in the specification; further

numerous other endotoxins are known in the art, and their structures studied, citing Li et al (response pg 18-19).

This is not found persuasive because this recitation does not describe the structural feature responsible for the claimed function.

Applicant urges that they have provided exemplary sequences, variants and fragments, and skilled artisan could envision the claimed sequences (response pg 19).

This is not found persuasive. Neither the exemplary sequences nor the fragments describe the structure of nucleic acids with 95% identity to SEQ ID NO: 1, 2, 4 or 6 and encoding proteins with 299 amino acid substitutions. No functional variants encoding proteins with 299 amino acid substitutions are described.

Applicant urges that the specification provides the structural features of nucleic acid that retain pesticidal activity because they recite a percent identity (response pg 19-20).

This is not found persuasive because not all nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6 will encode proteins with pesticidal activity. The specification does not describe the structure required for the recited function, nor does it describe the structural features that distinguish pesticidal protein-encoding nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6 from other nucleic acids with 95% identity to SEQ ID NO:1, 2, 4 or 6 or pesticidal proteins with 95% identity to SEQ ID NO:3, 5 or 7 from other proteins with 95% identity to SEQ ID NO:3, 5 or 7.

Applicant urges that the claim recites functional characteristics, that is, that they encode proteins with pesticidal activity; the art and the specification provide standard assays for such activity. Further, the specification teaches fragments, SEQ ID NO:4, which encodes a fragment

of SEQ ID NO:3, and SEQ ID NO:6, which encodes a fragment of SEQ ID NO:1 (response pg 19).

This is not found persuasive because the relationship between structure and pesticidal function was not described in the specification. SEQ ID NO:4 encodes SEQ ID NO:5, a 690 amino acid long fragment of the 693 amino acid long SEQ ID NO:3; SEQ ID NO:4 does not describe nucleic acids within the full scope of the claims. The specification suggests that SEQ ID NO:7, the protein encoded by SEQ ID NO:6, would not be toxic to insects (pg 38, lines 9-10), and no assay for it is taught.

7. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.
The rejection is repeated for the reasons of record as set forth in the Office action mailed 14 February 2006, as applied to claims 3, 11 and 19. Applicant's arguments filed 12 May 2005 have been fully considered but they are not persuasive.

In claim 11, it is not clear if the seed is transgenic because it comprises the vector or if it transgenic because it was transformed with some other nucleic acid.

Applicant urges that claim 11 has been amended to recite "the" plant of claim 9; because of dependency the claim now describes seed derived from a plant comprising the nucleic acid of claim 1 (response pg 21).

This is not found persuasive because not all seeds produced from plants comprising the nucleic acid of claim 1 will also corpses that nucleic acid; if the plant has only one copy of the nucleic acid, only half the progeny will comprise the nucleic acid.

Conclusion

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg, can be reached at (571) 272-0975.

The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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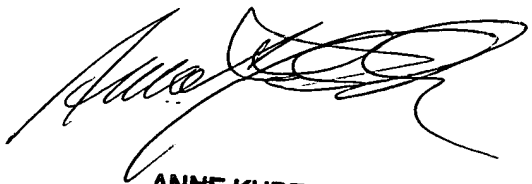
Anne Kubelik, Ph.D.
September 25, 2006



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER